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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/632,147	07/31/2003	Assaf Govari	BIO-5021	1868
27777	7590	04/07/2006	EXAMINER	
PHILIP S. JOHNSON JOHNSON & JOHNSON ONE JOHNSON & JOHNSON PLAZA NEW BRUNSWICK, NJ 08933-7003			KRAMER, NICOLE R	
			ART UNIT	PAPER NUMBER
			3762	

DATE MAILED: 04/07/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/632,147

Applicant(s)

GOVARI, ASSAF

Examiner

Nicole R. Kramer

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 February 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5,8,10-13,18-20,23,26 and 27 is/are pending in the application.
- 4a) Of the above claim(s) 6,7,9,14-17,21,22,24 and 25 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5,8,10-13,18-20,23,26 and 27 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 31 July 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>11/10/03; 12/13/04</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of Species 2 in the reply filed on 2/8/06 is acknowledged.
2. Upon review of the claims, Examiner deems claims 1-4, 8, 10-11, 18, 23, and 26-27 generic. Claims 5, 12-13, and 19-20 are included in the elected species group. Accordingly, claims 1-5, 8, 10-13, 18-20, 23, and 26-27 are presently examined.
3. Examiner notes that Applicant listed claims 24-25 as readable on elected species. Claim 24 relates to a sensing the position coordinates of the device, and is believed to belong to Species Group 1, since position sensing is described in relation to Fig. 3. Claim 25 relates to a fixing the casing to an invasive medical tool and determining the location of the tool within the body, and is believed to belong to Species Group 1, since position sensing is described in relation to Fig. 3.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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5. Claims 1, 3, 5, 8, 10-11, 18, 23, and 26-27 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent Application Publication 2002/0095195 ("Mass et al.").

Mass et al. discloses an implantable medical device (100), the device comprising an outer casing comprising an insulating material (insulating material 102) and an electrically conductive material (metallic device housing halves 101a and 102b) and a transmitter encapsulated in the casing (RF drive circuitry 330 includes an RF transmitter and receiver; see paragraph 0014). The transmitter is coupled to the conductive material so that the electrically conductive area of the casing serves as an antenna for transmitting the signal to a receiver outside the body (RF drive circuitry 330 is connected by a transmit/receive switch 333 to the dipole antenna formed by housing portions 101a and 101b; see paragraph 0014).

With respect to claim 3, Mass et al. discloses that the device housing is metallic (see paragraph 0013). Since the housing halves themselves are metallic, the electrically conductive material is necessarily arranged to fill an entire thickness of the casing between the inner surface and the electrically conductive area of the outer surface.

With respect to claim 5, Examiner notes that the recitation that "the electrically-conductive area is configured to contact a metal implant within the body of the mammalian subject while transmitting the signal" is a statement of intended use. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably

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distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. The IMD of Mass et al. is capable of contacting a metal implant within the body, and thus anticipates claim 5.

With respect to claims 8, 10-11, 23, and 26-27, Mass et al. discloses that the IMD contains therapy circuitry, which may be used for physiological monitoring (see paragraph 0013). Physiological monitoring necessarily requires a sensor. As one example, Mass et al. describes a cardiac rhythm management device (i.e., a pacemaker) that includes sensing circuitry connected to electrodes for the control of heart rhythm (see paragraph 0014). Such sensing circuitry may be considered a sensor.

With respect to claim 18, the IMD of Mass et al. necessarily performs the method of claim 18.

6. Claims 1-2, 4-5, 8, 10-11, 18, 23, and 26-27 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 5,861,019 ("Sun et al.").

Sun et al. discloses an implantable medical device (IPG 12) having a micro-strip or patch antenna (the patch antenna is formed of three layers: an electrically conductive, radiator patch layer 30/30', a conductive ground layer 48/48', and dielectric layer 36/36' sandwiched between the patch layer and the ground layer; see col. 10, lines 21-47) formed on the exterior surface of the housing or casing. Since the patch antenna is deposited on or embedded into the exterior surface of the IPG housing (see col. 10m lines 62-65), Examiner considers the patch antenna to be part of the

housing/casing. According, the IPG casing is considered to include an insulating material (dielectric layer 36/36') and an electrically conductive material (electrically conductive patch radiator layer 30/30') and a transmitter encapsulated in the casing (telemetry transmitter 42 and receiver 44 are encapsulated within the IMD housing; see col. 9, lines 25-35). The transmitter is coupled to the conductive material so that the electrically conductive area of the casing serves as an antenna for transmitting the signal to a receiver outside the body (the radiator patch layer 30/30' is coupled to transceiver circuitry including transmitter 42 and receiver 44 within the IMD housing; see col. 9, lines 25-35).

With respect to claim 2, Sun et al. discloses that the dielectric material may be ceramic (see col. 13, lines 2-5).

With respect to claim 4, Sun et al. discloses an embodiment in which the electrically conductive radiator patch layer 30/30' is formed on the exterior surface of the ceramic housing 13' of the IPG, and ground layer 48' is formed as a conductive layer on the interior surface of the housing 13', such that the ceramic IPG housing constitutes and provides the dielectric substrate layer sandwiched between the ground layer and the radiator patch layer (see col. 15, lines 45-55). In such an embodiment, the conductive material (layer 30) is arranged in a layer overlying the insulating material (ceramic housing 13') as required by claim 4.

With respect to claim 5, Examiner notes that the recitation that "the electrically-conductive area is configured to contact a metal implant within the body of the mammalian subject while transmitting the signal" is a statement of intended use. A

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recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. The IMD of Sun et al. is capable of contacting a metal implant within the body, and thus anticipates claim 5.

With respect to claims 8, 10-11, 23, and 26-27, Sun et al. discloses that data to be transmitted from the IPG to the external programmer includes sensor output signals (see col. 2, lines 8-25).

With respect to claim 18, the IMD of Sun et al. necessarily performs the method of claim 18.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claim 2 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent Application Publication 2002/0095195 ("Mass et al.").

As described above, Mass et al. discloses an IMD in which the electrically conductive housing portions of the casing form a dipole antenna. Mass et al. discloses that the electrically conducting portions (101a and 101b) of the housing are separated by a layer of insulating material 102 (see paragraph 0013), but fails to specifically

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disclose that the insulating material may be a ceramic material or a plastic material.

Both ceramics and plastic materials are well known insulating materials used in the medical device art. It would have been obvious to one having ordinary skill in the art at the time of applicant's invention to utilize either ceramic or plastic material as insulating material 102 of Mass et al. since both materials are well known in the medical device art for their insulating characteristics.

9. Claims 12-13 and 19-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,447,448 ("Ishikawa et al.") in view of U.S. Patent Application Publication 2002/0095195 ("Mass et al.").

Ishikawa et al. teaches an implantable orthopedic sensor in the shape of a spherical ball which can be implanted within a metallic, orthopedic insert for sensing various physiological and positional parameters, such as monitoring the integrity of a implant coupling, the temperature generated by action of a mechanical joint, or pressure exerted on the joint interface (see Fig. 3 and associated text at col. 7, lines 1-22). The orthopedic sensor (i.e., ball 110) includes a processor 140, a radio communication circuit 150, and one or more sensors 160. Ishikawa et al. fails to disclose that conductive material of the outer surface of the casing serves as an antenna for transmitting the signal to a receiver outside the body. Mass et al. discloses an IMD, such as a physiological monitor (see paragraph 0013) in which electrically conductive housing portions of the IMD casing form a dipole antenna. Mass et al. teaches that forming the antenna from conductive portions of the housing results in a greater

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bandwidth, which is easier to tune and is usable over a greater range of frequencies once it is tuned (see paragraph 0012). Further, the dipole antenna of Mass et al. does not require any special implantation procedures and is a rigid structure that is resistant to breakage or deformation (see paragraph 0011). It would have been obvious to one having ordinary skill in the art at the time of applicant's invention to modify the implantable orthopedic sensor of Ishikawa et al. such that electrically-conductive housing portions of the sensors form a dipole antenna as taught by Mass et al. in order to provide the orthopedic sensor with a greater bandwidth and a telemetry configuration that is resistant to breakage or deformation.

With respect to claim 19, when the electrically conductive casing (as modified by Mass et al. above) is placed in contact with the metallic orthopedic hip prosthesis (see Fig. 3 of Ishikawa et al), the gain of the antenna will necessarily be increased in transmitting the signal.

Conclusion

10. The art made of record and not relied upon is considered pertinent to applicant's disclosure:

U.S. Patent Application No. 2006/0009856, which is not prior art to the present application, teaches electrically coupling a wireless communication module to a metallic implant so that the implant component operates as an antenna.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nicole R. Kramer whose telephone number is 571-272-8792. The examiner can normally be reached on Monday through Friday, 8 a.m. to 4:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on 571-272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

NRK

NRK

3/16/06

G. Manuel
George Manuel
Primary Examiner